

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) 11 APRIL 2005 (11.04.2005)

Applicant's or agent's file reference  
PCTA9407-17

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/KR2004/001989

International filing date (day/month/year)

06 AUGUST 2004 (06.08.2004)

Priority date(day/month/year)

International Patent Classification (IPC) or both national classification and IPC

IPC7 A61K 9/127, A61P 17/16

Applicant

BIOSPECTRUM, INC. et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR



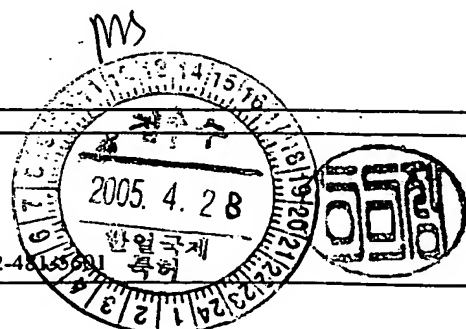
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/KR2004/001989

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing  
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format.  
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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**WRITTEN OPINION OF THE  
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International application No.

PCT/KR2004/001989

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims	1 - 10	YES
	Claims		NO
Inventive step (IS)	Claims	1 - 10	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 - 10	YES
	Claims		NO

**2. Citations and explanations :**

The following documents are referred to in this report:

D1: KR 2001-0083712 A (01. 09. 2001)  
D2: KR 1990-7396 A (01. 06. 1990)  
D3: KR 1999-0070886 A (15. 09. 1999)  
D4: KR 2004-0027829 A (01. 04. 2004)  
D5: US 2004/0120918 A1 (24. 06. 2004)

**1. Novelty and Inventive Step**

Claims 1-10 of the present invention relate to a multilayered liposome made of squalane, sterol, ceramide, neutral lipid or oil, fatty acid, and lecithin in a specific ratio; a preparation method thereof; and a transdermal composition comprising the said liposome incorporating biologically active ingredients.

D1 discloses a liposomal cosmetic composition comprising lecithin, oil, sterol, and ceramide.

D2 discloses a stabilized liposomal composition comprising squalane.

D3 discloses that a cosmetic composition of liposomal microspheres comprising silicone oil, fatty acid, etc.

D4 discloses a nano-liposomal composition made of lecithin, ceramide, and sterol.

D5 discloses cosmetic or dermatopharmaceutical compositions of ceramides and polypeptides.

None of D1-D5 discloses a multilayered liposome made of squalane, sterol, ceramide, neutral lipid or oil, fatty acid, and lecithin in a specific ratio of the present invention.

In addition, it is not easily expected by a man skilled in the art that the multilayered liposome made of the said components in a specific ratio can be made without a high-pressure microfluidizer.

Therefore, the novelty and inventive step of claims 1-10 in the present invention can be acknowledged over D1-D5 [Article 33(2) and 33(3) PCT].

**2. Industrial Applicability**

The subject-matter of claims 1-10 appears to be industrially applicable [Article 33(4) PCT].

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